#21

specifically at ex-offenders, an additional supplementary module will be administered by Audio-CASI. Similarly, an additional supplementary module will be administered by Audio-CASI in the site operating a program aimed at survey respondents with mental health problems. Finally, in the two-generation sites (two of the six sites), survey respondents will complete a two-generation survey administered by a Computer Assisted Personal Interview (CAPI). Approximately 12,000 respondents will complete the core survey, 2,000 will complete the criminal justice module, 2,000 will complete the mental health module, and 4,000 will complete the two-generation CAPI survey.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Audio-CASI Core	12,000	1	10 minutes or .17 hrs	2,000
Criminal Justice Module	2,000	1	10 minutes or .17 hrs	333.33
Mental Health Module	2,000	1	10 minutes or .17 hrs	333.33
Two Generation	4,000	1	30 minutes or .5 hrs	2,000
Estimated Total Annual Burden Hours				4,666.66

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 6, 2003.

Gerald L. Fralick,

Director, Office of Information Systems.

[FR Doc. 03-3446 Filed 2-12-03; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03F-0023]

Kerry, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Kerry, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of gum arabic as a thickener, emulsifier, or stabilizer in the manufacture of creamers for use in alcoholic beverages at a maximum level of use of 20 percent.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (S-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3071.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 1A4730) has been filed by Kerry, Inc., c/o Bell, Boyd, and Lloyd LLC, Three First National Plaza, 70 West Madison St., suite 3300, Chicago, IL 60602-4207. The petition proposes to amend the food additive regulations in part 172 *Food Additives Permitted for Direct Addition to Food for Human Consumption* (21 CFR part 172) to provide for the safe use of gum arabic as a thickener, emulsifier, or stabilizer in the manufacture of creamers for use in alcoholic beverages at a maximum level of use of 20 percent.

The food additive petition filed as FAP 1A4730 was initially filed as a generally recognized as safe (GRAS) affirmation petition GRP 3G0287 as announced in a notice that was published in the **Federal Register** of October 13, 1983 (48 FR 46626) (The GRAS affirmation petition was filed by Beatrice Foods Co., now Kerry, Inc.). Kerry, Inc., requested in a letter dated September 6, 2001, that FDA convert the GRAS affirmation petition (GRP 3G0287) to a food additive petition (FAP 1A4730).

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment.

Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 19, 2002.

Alan M. Rulis,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 03-3557 Filed 2-12-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E-1249]

Determination of Regulatory Review Period for Purposes of Patent Extension; Avandia

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for

Avandia and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Avandia (rosiglitazone maleate). Avandia is indicated for use in combination with a sulfonylurea in patients with type 2 diabetes mellitus when diet and exercise with either single agent does not achieve adequate glycemic control. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Avandia (U.S. Patent No. 5,002,953) from Smithkline Beecham Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 26, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Avandia represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Avandia is 2,042 days. Of this time, 1,859 days occurred during the testing phase of the regulatory review period, while 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* October 23, 1993. The applicant claims October 22, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 23, 1993, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* November 24, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for Avandia (NDA 21–071) was initially submitted on November 24, 1998.

3. *The date the application was approved:* May 25, 1999. FDA has verified the applicant's claim that NDA 21–071 was approved on May 25, 1999.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,021 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written comments and ask for a redetermination by April 14, 2003. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 12, 2003. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit a single copy. Copies are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–3555 Filed 2–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1239]

Determination of Regulatory Review Period for Purposes of Patent Extension; Rapamune

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Rapamune and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.